



**UNITED STATES DEPARTMENT OF COMMERCE  
Patent and Trademark Office**

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/373,182 08/12/99 MCCLURE

K PC10240A

023913  
PFIZER INC  
235 E 42ND STREET  
NEW YORK NY 10017

HM12/1201

EXAMINER

WEBER, J

ART UNIT

PAPER NUMBER

1651

DATE MAILED:

12/01/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.

09/373,182

Applicant(s)

MCCLURE ET AL.

Examiner

Jon P. Weber

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1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-79 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claims 1-79 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

## Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_
- 18) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

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*Status of the Claims*

Claims 1-79 have been presented for examination.

*Election/Restrictions*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- prop I
- I. Claims 1-54, drawn to hydroxamate compounds, classified, for example, in class 544, subclasses 8, 59 and 106.
  - II. Claim 55, drawn to inhibiting production of TNF with the compounds of claim 1, classified, for example, in class 514, subclasses 227.5, 231.2, and 255.
  - III. Claims 56 and 59, drawn to a method of treating diseases with the compounds of claim 1, classified, for example, in class 514, subclasses 227.5, 231.2, and 255.
  - IV. Claims 57-58, drawn to a method of inhibiting cleavage of TNF with the compounds of claim 1, classified, for example, in class 435, subclass 212.
  - V. Claims 60-61, drawn to a method of inhibiting cleavage of TNF with compounds that inhibit TACE > MMP1, classified in class 435, subclass 183+.
  - VI. Claims 62 and 66-67, drawn to a method of treating diseases with compounds that inhibit TACE > MMP1, classified in class 514, subclass ?.
  - VII. Claims 63-64, drawn to a method of inhibiting cleavage of TNF with compounds that inhibit TACE > MMP13, classified in class 514, subclass ?.
  - VIII. Claim 65, drawn to a method of inhibiting cleavage of TNF with compounds the inhibit TACE and aggrecanase > MMP1, classified in class 514, subclass ?.
  - IX. Claims 68-69, drawn to a method of treating arthritis with compounds that inhibit TACE and MMP13 > MMP1, classified in class 514, subclass ?.
- OR Elect Prop II

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- Prod*  
III
- X. Claims 70-71, drawn to a method of treating arthritis with compounds that inhibit aggrecanase > MMP1, classified in class 514, subclass ?.
  - XI. Claims 72-75, drawn to a method of treating arthritis with compounds that inhibit aggrecanase and MMP13 > MMP1, classified in class 514, subclass ?.
  - XII. Claims 76-77, drawn to a method of treating arthritis with compounds that inhibit aggrecanase and TACE > MMP1, classified in class 514, subclass ?.
  - XIII. Claims 78-79, drawn to a method of treating arthritis with compounds that inhibit aggrecanase, TACE and MMP13 > MMP1, classified in class 514, subclass ?.

Many of the subclasses are unknown because no specific compounds are identified.

The inventions are distinct, each from the other because of the following reasons:

Inventions Group I and Groups II, III and IV are related as product and process of use.

The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case Groups II-IV are different methods of using the product of Group I.

Inventions V and VI-XIII are all unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions each of the methods requires compounds having different functional activities and/or are used in different methods. There is no reason why the same compounds would meet the specific different functional limitations of the different Groups.

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Inventions Groups I-IV and V-XIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions require specifically defined compounds or functionally defined compounds.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, their separate status in the art because of their recognized divergent subject matter, and because the search required for Group I is not required for Group II-XIII, for example, restriction for examination purposes as indicated is proper.

Should any of Groups I, VI, VII, IX, XI, XII or XIII be elected, claims 1, 62, 63, 68, 72, 76 and 78 are generic to a plurality of disclosed patentably distinct species comprising a) specific hydroxamate compounds in claim 1, b) small molecules, agents or hydroxamates in claims 62, 63, 68, 72, 76 and 78. Applicant is further required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete **must** include an election of the invention to be examined and species if necessary even though the requirement be traversed (37 CFR 1.143).

Applicant is also reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

It was noted that amino acid sequences were present at page 41, 45, 46, 47 and 50 which will need compliance with the sequence rules. It is suggested that a sequence listing be prepared and submitted with the response to this Office action in advance of a formal requirement from the Office to expedite prosecution.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon P. Weber whose telephone number is 703-308-4015. The examiner can normally be reached on 1st Fri, 9/5/4.

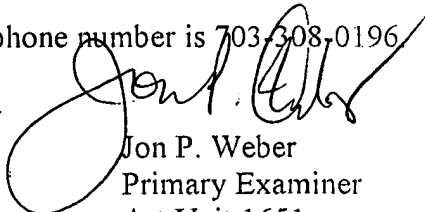
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 703-308-4743. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Jon P. Weber  
Primary Examiner  
Art Unit 1651

JPW  
November 30, 2000